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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jean-Pierre Cougoulic

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EXAMINER

PEPITONE, MICHAEL F

ART UNIT

PAPER NUMBER

1796

NOTIFICATION DATE

DELIVERY MODE

01/06/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/540,756	Applicant(s) COUGOULIC, JEAN-PIERRE	
	Examiner MICHAEL PEPITONE	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-28,36 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-28,36 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/26/09 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Mills *et al.* (US 6,482,584).

Regarding claims 21-22: Cougoulic teaches a material for medical or veterinary use designed for the execution of endo-bone implants, bone prostheses, and dental implants (1:5-12), wherein the material is in the form of a molded part made of a biocompatible thermoplastic polymer {binder} containing at least one compound for adding calcium or phosphorous (1:35-62; 2:56-60; 3:20-4:20), wherein the material comprises a thermoplastic polymer in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components

Art Unit: 1796

designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite [instant claim 22] (1:55-2:3; 2:61-3:14). Cougoulic teaches molding operations (2:56-60; 3:1-8; 4:13-48).

Cougoulic does not teach surface pickling or decontamination operations on the molded material. However, Mills *et al.* teaches a method of cleaning/sterilizing implants, as well sterile packaging of the implant (1:5-14; 3:65-4:11; 14:34-55), comprising subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which can undergo {elevated} temperature and pressure cycles {autoclave} (4:14-65), wherein the chamber permits sonication of the contents (4:52-54; 6:49-58; 8:14-51). The surface treatment includes solutions of: HCl (14:5-21, Table II (J)), acetone (14:5-21, Table II (J)); hydrogen peroxide (4:14-18), sodium hypochlorite (14:5-12), Betadine or isopropanol {decontaminating product}(4:14-18; 14:5-21), and sterile water (11:28-33, Tables I and II) [i.e. a process of pressure cycling or oscillation, employing a variety of cleaning and sterilization solutions (8:15-51, Tables I-II) {sterilization via autoclave} with concurrent ultrasonic bombardment {surface pickling}, wherein the process steps can be repeated (4:35-37; 8:44-46), and the cleaning fluid is removed to waste under positive pressure and the implant is rinsed under positive pressure and the rinse fluid is removed under positive pressure (11:24-35); subsequently the implant material is packaged in a sterile environment (14:33-55)]. Cougoulic and Mills *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents

Art Unit: 1796

{surface pickling}, as taught by Mills *et al.* in the invention of Cougoulic, and would have been motivated to do so since Mills *et al.* suggests that such processes provide penetrating sterilization of the implant (4: 65-5:14; 8:14-51).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance [instant claim 21], would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Regarding claims 23-24: Cougoulic teaches the binder is a thermoplastic polymer [instant claim 23], specifically polyetheretherketone (PEEK) [instant claim 24] (2:23-43).

Regarding claim 26: Cougoulic teaches TiO_2 (2:44-50).

Regarding claim 27: Cougoulic teaches chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and metallic oxide (TiO_2) (2:61-3:14).

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Mills *et al.* (US 6,482,584), as applied to claim 21 above, and in further view of Ellingsen *et al.* (US 2002/0111694).

Art Unit: 1796

Regarding claim 25: Cougoulic and Mills *et al.* renders the basic claimed composition obvious [as set forth above with respect to claim 21].

Cougoulic does not teach cellulose as a binder. However, Ellingsen *et al.* teaches medical prosthetic devices and implants (bone and dental) comprising cellulose as a biopolymer (§ 2, 9, and 19). Cougoulic and Ellingsen *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined cellulose, as taught by Ellingsen *et al.* in the invention of Cougoulic, and would have been motivated to do so since Ellingsen *et al.* suggests that cellulose provides tissue resilience, strength, rigidity, and integrity of the extra-cellular matrix (§ 21).

Claims 28 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Mills *et al.* (US 6,482,584).

Regarding claims 28 and 36: Cougoulic teaches a method for preparing a material for medical or veterinary use (1:5-12), wherein the material is prepared by mixing a mixture comprising a thermoplastic polymer {polyetheretherketone (PEEK) (2:23-43)} in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and subjected to molding operations (1:35-2:3; 2:61-3:14; 3:43-4:15).

Cougoulic does not teach surface pickling or decontamination operations on the molded material, nor packaging aseptically of the decontaminated material [instant claim 28]. However, Mills *et al.* teaches a method of cleaning/sterilizing implants, as well sterile packaging of the

Art Unit: 1796

implant (1:5-14; 3:65-4:11; 14:34-55), comprising subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which can undergo {elevated} temperature and pressure cycles {autoclave} [instant claim 28] (4:14-65), and which permits sonication of the contents (4:52-54; 6:49-58; 8:14-51). The surface treatment includes solutions of: HCl (14:5-21, Table II (J)), acetone (14:5-21, Table II (J)); hydrogen peroxide (4:14-18), sodium hypochlorite (14:5-12), Betadine or isopropanol {decontaminating product} [instant claim 36] (4:14-18; 14:5-21), and sterile water (11:28-33, Tables I and II). Cougoulic and Mills *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling}, and sterile packaging of the implant, as taught by Mills *et al.* in the invention of Cougoulic, and would have been motivated to do so since Mills *et al.* suggests that such processes provide penetrating sterilization of the implant (4:65-5:14; 8:14-51).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance [instant claim 28], would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's

Art Unit: 1796

position; and (2) it would be the Office's position that the application contains inadequate disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cougoulic (US Patent 5,872,159) in view of Mills *et al.* (US 6,482,584).

Regarding claim 41: Cougoulic teaches a method for preparing a material for medical or veterinary use (1:5-12), wherein the material is prepared by mixing a mixture comprising a thermoplastic polymer {polyetheretherketone (PEEK) (2:23-43)} in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite, and subjected to molding operations (1:35-2:3; 2:61-3:14; 3:43-4:15).

Cougoulic does not teach surface pickling or decontamination operations on the molded material, nor packaging aseptically of the decontaminated material. However, Mills *et al.* teaches a method of cleaning/sterilizing implants, as well sterile packaging of the implant (1:5-14; 3:65-4:11; 14:34-55), comprising subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which can undergo {elevated} temperature and pressure cycles {autoclave} (4:14-65), wherein the chamber permits sonication of the contents (4:52-54; 6:49-58; 8:14-51). The surface treatment includes solutions of: HCl (14:5-21, Table II (J)), acetone (14:5-21, Table II (J)); hydrogen peroxide (4:14-18), sodium hypochlorite (14:5-12), Betadine or isopropanol {decontaminating product}(4:14-18; 14:5-21), and sterile water (11:28-33, Tables I and II) [i.e. a process of pressure cycling or oscillation, employing a

Art Unit: 1796

variety of cleaning and sterilization solutions (8:15-51, Tables I-II) {sterilization via autoclave} with concurrent ultrasonic bombardment {surface pickling}, wherein the process steps can be repeated (4:35-37; 8:44-46), and the cleaning fluid is removed to waste under positive pressure and the implant is rinsed under positive pressure and the rinse fluid is removed under positive pressure (11:24-35); subsequently the implant material is packaged in a sterile environment (14:33-55)]. Cougoulic and Mills *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation medical (bone and dental) implants. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined subjecting the implant to an oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling}, and sterile packaging of the implant, as taught by Mills *et al.* in the invention of Cougoulic, and would have been motivated to do so since Mills *et al.* suggests that such processes provide penetrating sterilization of the implant (4: 65-5:14; 8:14-51).

The Office realizes that all the claimed effects or physical properties are not positively stated by the reference. However, the reference teaches all of the claimed reagents and prepared under similar conditions. Therefore, the claimed effects and physical properties, i.e. surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance [instant claim 41], would implicitly be achieved by a composition with all the claimed ingredients. If it is the applicants' position that this would not be the case: (1) evidence would need to be presented to support applicant's position; and (2) it would be the Office's position that the application contains inadequate

Art Unit: 1796

disclosure that there is no teaching as to how to obtain the claimed properties and effects with only the claimed ingredients.

Response to Arguments

Applicant's arguments with respect to claims 21-41 have been considered but are moot in view of the new ground(s) of rejection.

Cougoulic (US 5,872,159) was relied on for disclosing a material for medical or veterinary use designed for the execution of endo-bone implants, bone prostheses, and dental implants, wherein the material is in the form of a molded part made of a biocompatible thermoplastic polymer {binder} [PEEK] in an amount of at least 65 weight% and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate and calcium hydroxyapatite (1:55-2:3; 2:61-3:14; 3:45-4:47) {see above}.

Mills *et al.* (US 6,482,584) was relied on for disclosing cleaning/sterilizing implants via oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface pickling} and provides penetrating sterilization of the implant {see above}.

The examiner takes the position that the combined teaching of Cougoulic (US '159) {a molded implant containing a thermoplastic polymer {PEEK} in an amount of at least 65 weight% of the composition and contains 10-35 weight% of chemical components designed for fostering biological integration, such as tricalcium phosphate, calcium hydroxyapatite} and Mills *et al.* (US '584) {cleaning/sterilizing implants via oscillation of pressure in the presence of various cleaning solutions in a chamber which permits sonication of the contents {surface

Art Unit: 1796

pickling}} would afford an implant having a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance. If it is the applicants' position that this would not be the case, evidence {data} would need to be presented to support applicant's position. Additionally, evidence would need to be provided for a showing of unexpected results and the prior art of record.

In response to applicant's argument that the claimed material contains a surface with emerging crystallized calcium phosphate that is resorbable after implantation to insure an efficient biocompatibility in terms of biological acceptance, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art (i.e. penetrating sterilization of the implant {surface pickling}) cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Ellingsen *et al.* (US 2002/0111694) was relied on for disclosing medical prosthetic devices and implants (bone and dental) comprising cellulose as a biopolymer (§ 2, 9, and 19).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pepitone whose telephone number is 571-270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1796

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MFP
30-December-09

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796